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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,060	03/10/2004	Alec Bobroff	HM-04-PT-03-NP	5665

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HAEMONETICS CORPORATION
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BRAINTREE, MA 02184-9114

EXAMINER

GIBSON, KESHIA L

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/798,060	Applicant(s) BOBROFF ET AL.	
	Examiner Keshia Gibson	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12, drawn to a postoperative fluid monitoring and alert system, classified in class 604, subclass 319.
 - II. Claim 13, drawn to a method of monitoring postoperative fluid drainage, classified in class 604, subclass 317.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus could be used in another process, such as vacuum cleaning or carpet shampooing a living quarters.
3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.
4. This application contains claims directed to patentably distinct species. In the event that applicant elects Group I, the claims are further subject to the following election of species:

Species I. The system having vacuum reservoir as a closed tank attached to a compressor.

Species II. The system having vacuum reservoir as a facility-wide source of suction.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-4 and 7-12 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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5. During a telephone conversation with John Perullo on 9/19/05 a provisional election was made with traverse to prosecute the invention of Group I, Species 1, claims 1-5 and 7-12. During the phone call, Mr. Perullo explained that the claimed invention and those similar to it usually comprise a closed tank, which is then connected to a facility-wide system; and, therefore, was objecting to the election of species requirement. Examiner explained that the claims had been interpreted to mean that the system was to have one or the other, not both, but was not completely sure that this was the case. Upon review of the application and in view of applicant's clarification of the claimed invention, Examiner agrees with the applicant and has therefore removed the election of species requirement. The election between Groups I and II still remains. Affirmation of this election must be made by applicant in replying to this Office action. Claim 13 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

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with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Drawings

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "34" has been used to designate both device housing and array of lights. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5, 7-9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. (US 5,153,828).

In regard to Claims 1-5 and 7-9, Inoue et al. disclose a fluid monitoring and alert system 10 comprising a fluid collection device—having a drain tube 2, a vacuum reservoir 13, a suction pathway 41/others—vacuum pump (compressor) 17, sensors 40, 71, 73, a controller 18, an audible alarm 69, a visual display 12, and a valve 43 (whole document). The system records and displays data related to the system, including pressure data. The controller monitors the pressure and controls the valve so as to maintain a certain level of vacuum within the system (especially column 6, lines 13-27, column 7, lines 58-68).

In regard to Claim 11, it has been held that a recitation with respect to the manner in which a claimed invention is intended to be employed does not differentiate the claimed invention from a prior art satisfying the claimed structural limitations. *Ex parte Maham*, 2 USPQ2d 1647 (1987). *In re Paulsen*, 30 F.3d 1475, 31 USPQ 2d 1671 (Fed. Cir. 1994). Therefore, the system is considered capable of being used in the manner claimed.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al.

In regard to Claim 12, Inoue et al. disclose that data, such as the amount of blood collected, is to be displayed on the visual display but do not expressly disclose the intervals at which this data is to be sampled or displayed. However, the interval at which the data is sample affects the accuracy of the information displayed to the user. As such, the interval at which data is collected and/or displayed to the user is considered to be a result effective variable. Thus, it would have been obvious to one of ordinary skill in the art to have the data display the volume of liquid collected in intervals of fifteen minutes, since it has been held that discovering an optimum value of a result effective

variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. in view of Killian et al. (US 5,876,387).

In regard to Claims 6, Inoue et al. disclose the claimed invention but do not expressly disclose that the vacuum reservoir is joined to a facility-wide source of suction. Killian et al. discuss a suction system to be used in a medical facility comprising a vacuum chamber and pump. Killian et al. discuss that the system is connected to a central suction facility in case of failure of the vacuum pump (column 1, lines 39-64). One would have been motivated to modify the system of Inoue et al. to have the vacuum reservoir connected to a central suction facility, as taught by Killian et al., since doing so would allow for a replacement source of suction in cause of failure of the vacuum pump. Thus, it would have been obvious to one of ordinary skill in the art to modify Killian et al. to have the vacuum reservoir connected to a facility-wide source of suction, as taught by Killian et al., since doing so would allow for a replacement source of suction in cause of failure of the vacuum pump.

15. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. in view of Valerio et al. (US 5,989,234).

In regard to Claim 10, Inoue et al. disclose the claimed invention but do not expressly disclose that the system comprises an autotransfusion device. Valerio et al. disclose a system for draining and collecting fluid from a body cavity comprising a vacuum pump

and chamber. Valerio et al. disclose that the device can be modified to serve as an autotransfusion device since reinfusing the patient's own blood is advantageous given today's concerns with communicable diseases (column 17, lines 22-29). (Also see Blankenship et al. US 5,116,312, column 1, lines 28-43). Thus, it would have been obvious to one of ordinary skill in the art to modify the system of Inoue et al. to comprise an autotransfusion device, as taught by Valerio et al., since doing so would provide the additional advantages of transfusion a patient with their own blood, or other bodily fluid.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lichtenstein (US 4,464,172), Antwiler (US 5,665,061), Lord (US 6,749,592 and US 2002/0193761), and Phung (US 2002/0030322), Jespersen (US 4,343,316), Blankenship et al. (US 4,658,834), Akkas et al. (US 4,735,610), Han et al. (US 5,891,051), Yam et al. (US 6,346,096).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keshia Gibson whose telephone number is (571) 272-7136. The examiner can normally be reached on M-F 8:30 a.m. - 6 p.m., out every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Keshia Gibson
Examiner
Art Unit 3761

klg 9/20/05

TATYANA ZALUKAEVA
PRIMARY EXAMINER

